157. (Amended) The method of claim 138 wherein the active electrode [terminal] is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the active electrode [terminal].

158. (Amended) The method of claim 138 further including positioning a distal end of a fluid supply shaft adjacent the active electrode [terminal], the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the active electrode [terminal].

REMARKS

Claims 80, 81 and 83-158 are pending. Applicant has canceled claim 159 and amended claims 90, 102, 138, 141, 143, 144, 146-148, 150-152, 157 and 158 to address the Examiner's 112 rejections on page 3 of the Office Action.

The majority of the claims stand rejected as being anticipated by Roos and Mulier. Applicant disagrees with these rejections. The instant application discloses and claims, in part, novel methods for performing, and systems used to perform, electrosurgery in the presence of electrically conductive fluid. For example, in performing electrosurgery according to the method of claim 80, the active and return electrodes of the instrument are both positioned near a tissue site in the presence of electrically conductive fluid, such as isotonic saline or Ringer's lactate. The return electrode is spaced away from the tissue such that electric current flows from the active electrode, through the conductive fluid, to the return electrode.

Independent claims 80 and 138 each require that the **return** electrode be spaced from the tissue. Mulier does not disclose or suggest this feature. Mulier discloses a monopolar electrosurgery device that requires a return pad attached to the patient's skin. Thus, the return electrode is always in contact with the tissue. Both electrodes 202 and 216 of the Mulier device are **active** electrodes that provide lesions in the tissue. Return electrodes are

not used to create lesions in tissue. Electrical current does not flow from electrode 202 to 216. Rather, the current flows from either, or both, electrode(s) 202, 216 to a return pad electrode (not shown).

Moreover, Mulier does not disclose that the conductive fluid creates a conductive path between the active and return electrodes. As discussed above, the return electrode in the Mulier device is a dispersive return pad placed on the outer surface of the patient' s skin. The conductive fluid in Mulier is used to expand the size of the lesion by spreading the effective area of the electrical current across a wider area (col. 2, lines 10-12). With active electrode 202, the conductive fluid helps create a helical ablation zone because it spreads the current density from the tip of the active electrode 202 to a wider zone. This ablation zone would not be created in such a fashion if electrode 216 were acting as a return electrode. Likewise, with active electrode 216, the conductive fluid creates a conductive path to the tissue, and helps create a conical ablation zone. Again, this conical ablation zone would not be created if the current were flowing from electrode 216 to electrode 202.

In light of the above, applicant requests that the Examiner withdraw the rejections over the Mulier reference.

Turning to Roos, independent claims 80 and 138 each require that both the active and return electrodes be operated in the presence of "electrically conductive fluid" during electrosurgery. Because the Roos '198 Patent does not disclose the use of electrically conductive fluid with any devices disclosed therein, it cannot anticipate any of the claims of this application.

The Roos '198 Patent never describes the use of "electrically conductive fluid" during electrosurgery. The Roos '198 Patent only discloses the use of an unspecified "washing liquid" that flows through the endoscope that houses the treatment and neutral electrodes. See Roos '198 Patent at 4:51-57, Fig. 1. The Roos '198 Patent does not state that the "washing liquid" that is supplied to the region of the surgical site is electrically conductive fluid. This omission is significant, because numerous non-conductive washing liquids, such as distilled water, glycine, sorbitol, and the like, have been used in electrosurgery and are still in use today. See, e.g., U.S. Patent No. 4,936,301 to Rexroth, et al. at 1:62-64 and 2:4-7.

In fact, the Roos '198 specification makes clear that the "washing liquid" delivered to the surgical site in the Roos '198 Patent is not electrically conductive. The Roos '198 Patent states at column 6, lines 51-53 that "the neutral electrode 11 in the form of a steel band rests on the tissue in large area form, so that good electrical contact is ensured." If the "washing liquid" were electrically conductive, there would be no need for the neutral electrode to rest on the tissue in large area form to ensure good electrical contact: electrical contact between the neutral electrode and the cutting electrode would be ensured by the "washing liquid" itself. The statement in the Roos '198 Patent that tissue contact with the neutral electrode is needed to ensure electrical contact plainly shows that the "washing liquid" described in the Roos '198 Patent could not have been electrically conductive.

A later-issued patent to the same named inventor, U.S. Patent No. 4,706,667 ("the Roos '667 Patent") to Roos, demonstrates unequivocally that the "washing liquid" disclosed in the Roos '198 Patent was not electrically conductive. Applicant has enclosed a copy of the Roos '667 patent for the convenience of the Examiner. The Roos '198 Patent claims priority to German Patent Application No. 2521719 ("German Patent Application"). The Roos '667 Patent explains at column 1 lines 14-29 that the device described in the German Patent Application (and thus in the Roos '198 Patent) did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive:

> In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for trouble free cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes.

According to the Roos '667 Patent, the device disclosed in the parent application to the Roos '198 Patent (and thus in the Roos '198 Patent itself) did not work because there was insufficient electrical contact between the neutral and cutting electrodes to cut tissue, even though the electrodes were in the "immediate vicinity" of one another. If the Roos '198 Patent had delivered electrically conducting fluid to the tissue site, such as isotonic saline, then the Roos '667 Patent surely would not have stated, as it did, that the cutting and neutral electrodes "only enter into electrical contact" with each other "via the secretion which is present during the cutting process." If Roos '198 had delivered electrically conducting fluid to the tissue site, there would have been an electrical connection between the cutting and neutral electrodes by virtue of the electrically conducting fluid itself, regardless of whether bodily secretions were present. Plainly, Roos '198 used non-conducting "washing liquid" and attempted to rely on bodily secretions from the cutting process to make the non-conductive "washing liquid" more conductive. According to the Roos '667 Patent, these secretions did not make the non-conductive "washing liquid" electrically conductive.

Significantly, the Roos '667 Patent did not solve the electrical contact problem described in the Roos '198 Patent by introducing electrically conducting fluid to the tissue site. Rather, the Roos '667 Patent solved the problem of poor conductivity by disclosing a device in which both the cutting and neutral electrodes were in physical contact with the tissue so that current could flow from the cutting electrode, through the tissue, and to the return electrode, not through electrically conducting fluid:

> The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small funnel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral electrode 11.

Because the Roos '198 Patent does not disclose or enable electrosurgical ablation in the presence of electrically conductive fluid, it cannot anticipate claims containing such an element. PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996)

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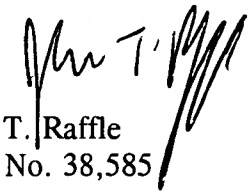
("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

In light of the above, applicant requests that the Examiner withdraw the rejections over Roos.

Applicant believes that all claims are in condition for allowance. If the Examiner has any questions or concerns regarding this matter, please call the undersigned at 408-736-0224.

Respectfully submitted,



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